UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,394	04/19/2004	John K. Jackson	UBC.P-033	5855

57381 7590 02/05/2007

Marina Larson & Associates, LLC
P.O. BOX 4928
DILLON, CO 80435

EXAMINER	
VIVLEMORE, TRACY ANN	
ART UNIT	PAPER NUMBER
1635	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
2 MONTHS	02/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/828,394
Filing Date: April 19, 2004
Appellant(s): JACKSON ET AL.

Marina T. Larson, Ph.D.

For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed July 20, 2006 appealing from the Office action mailed February 28, 2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows:

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner. The rejection of claim 6 for lacking written description and the provisional rejection of claims 6 and 7 on the grounds of obviousness-type double patenting.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

Kunkel, P. et al. "Inhibition of Glioma Angiogenesis and Growth *in vivo* by Systemic Treatment with a Monoclonal Antibody against Vascular Endothelial Growth Factor Receptor-2" Cancer Research 2001, vol 61 (September 15, 2001), pp. 6624-6628. This reference was made of record 2/28/06 and is present in IFW under the Prior Art tab.

6,383,808 Monia et al. 5-2002

6,900,187 Gleave et al. 5-2005

US 2003/0158130 Gleave et al. 8-2003

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 6 and 7 stand rejected under 35 U.S.C. 102(b) as anticipated by Monia et al. (US 6,383,808).

Claim 6 is directed to a method of reducing angiogenesis in a cancerous angiogenesis-related disease by administering to cells of the cancer a therapeutic oligonucleotide effective to reduce the amount of clusterin. Claim 7 limits the method to use of antisense oligonucleotides complementary to the sequence of human clusterin.

Monia et al. disclose antisense oligonucleotides that are targeted to and inhibit expression of clusterin. One of these, designated as SEQ ID NO: 18, is complementary to nucleotides 101-120 of human clusterin as shown in instant SEQ ID NO: 1.

Monia et al. disclose at column 2, lines 65-66 that gliomas are a disease associated with clusterin expression and at column 3, lines 40-46 a method of treating an animal having a disease associated with expression of clusterin using the antisense oligonucleotides of their invention. Gliomas are cancerous angiogenesis-related diseases as evidenced by Kunkel et al. (Cancer Research 2001), who teach on page 6624, first paragraph that gliomas exhibit angiogenesis.

Although silent with regard to the ability of their method to reduce angiogenesis in a cancerous angiogenesis related disease, Monia et al. disclose antisense oligonucleotides targeted to clusterin and direct their use to inhibit clusterin expression in animals suffering from gliomas. As stated in MPEP 2112, there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of the invention, but only that the subject matter is in fact inherent in the prior art reference:

> I. SOMETHING WHICH IS OLD DOES NOT BECOME PATENTABLE UPON THE DISCOVERY OF A NEW PROPERTY
> "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas*

Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). >In *In re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court held that the claimed promoter sequence obtained by sequencing a prior art plasmid that was not previously sequenced was anticipated by the prior art plasmid which necessarily possessed the same DNA sequence as the claimed oligonucleotides. The court stated that "just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel." *Id.*< See also MPEP § 2112.01 with regard to inherency and product-by-pro-cess claims and MPEP § 2141.02 with regard to inherency and rejections under 35 U.S.C. 103.

II. INHERENT FEATURE NEED NOT BE RECOGNIZED AT THE TIME OF THE INVENTION
There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure *at the time of invention*, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition by a person of ordinary skill in the art before the critical date and allowing expert testimony with respect to post-critical date clinical trials to show inherency); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004)("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention."); *Abbott Labs v. Geneva Pharms., Inc.*, 182 F.3d 1315, 1319, 51 USPQ2d 1307, 1310 (Fed.Cir.1999) ("If a product that is offered for sale inherently possesses each of the limitations of the claims, then the invention is on sale, whether or not the parties to the transaction recognize that the product possesses the claimed characteristics."); *Atlas Powder Co. v. Ireco, Inc.*, 190 F.3d 1342, 1348-49 (Fed. Cir. 1999) ("Because 'sufficient aeration' was inherent in the prior art, it is irrelevant that the prior art did not recognize the key aspect of [the] invention.... An inherent structure, composition, or function is not necessarily known.")>; *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 134344, 74 USPQ2d 1398, 1406-07 (Fed. Cir. 2005) (holding that a prior art patent to an anhydrous form of a compound "inherently" anticipated the claimed hemihydrate form of the compound because practicing the process in the prior art to manufacture the anhydrous compound "inherently results in at least trace amounts of" the claimed hemihydrate even if the prior art did not discuss or recognize the hemihydrate)<.

Therefore, because gliomas are a cancerous angiogenesis related disease, and Monia et al. teach administering antisense oligonucleotides targeted to clusterin to animals suffering from gliomas and it has since been discovered that inhibition of clusterin has the effect of reducing angiogenesis, the disclosure of Monia et al. anticipates the instant invention.

Claims 6-8 stand rejected under 35 U.S.C. 102(e) as anticipated by Gleave et al. (US 6,900,187).

Claim 6 is directed to a method of reducing angiogenesis in a cancerous angiogenesis-related disease by administering to cells of the cancer a therapeutic oligonucleotide effective to reduce the amount of clusterin. Claim 7 limits the method to

use of antisense oligonucleotides complementary to the sequence of human clusterin while claim 8 recites the antisense oligonucleotide is SEQ ID NO: 5.

Gleave et al. disclose and claim (see particularly column 6, lines 47-56 and claim 3) a method of treating prostate cancer in an individual comprising administration of an antisense oligonucleotide targeted to TRPM-2, another name for clusterin, that is SEQ ID NO: 4. This sequence is identical to the sequence designated as SEQ ID NO: 5 in the instant application.

Although silent with regard to the ability of their method to reduce angiogenesis in a cancerous angiogenesis related disease, Gleave et al. disclose administration of antisense oligonucleotides targeted to TRPM-2 to cells of prostate cancer, disclosed in the instant specification at page 4 as a cancerous angiogenesis-related disease. As stated in MPEP 2112, there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of the invention, but only that the subject matter is in fact inherent in the prior art reference:

> I. SOMETHING WHICH IS OLD DOES NOT BECOME PATENTABLE UPON THE DISCOVERY OF A NEW PROPERTY
> "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). >In *In re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court held that the claimed promoter sequence obtained by sequencing a prior art plasmid that was not previously sequenced was anticipated by the prior art plasmid which necessarily possessed the same DNA sequence as the claimed oligonucleotides. The court stated that "just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel." *Id.*< See also MPEP § 2112.01 with regard to inherency and product-by-pro-cess claims and MPEP § 2141.02 with regard to inherency and rejections under 35 U.S.C. 103.
>
> II. INHERENT FEATURE NEED NOT BE RECOGNIZED AT THE TIME OF THE INVENTION
> There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure *at the time of invention*, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition by a person of ordinary skill in the art before the critical date and allowing expert testimony with respect to post-critical date clinical trials to show inherency); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004)("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough

for inherent anticipation, even if that fact was unknown at the time of the prior invention."); *Abbott Labs v. Geneva Pharms., Inc.*, 182 F.3d 1315, 1319, 51 USPQ2d 1307, 1310 (Fed.Cir.1999) ("If a product that is offered for sale inherently possesses each of the limitations of the claims, then the invention is on sale, whether or not the parties to the transaction recognize that the product possesses the claimed characteristics."); *Atlas Powder Co. v. Ireco, Inc.*, 190 F.3d 1342, 1348-49 (Fed. Cir. 1999) ("Because 'sufficient aeration' was inherent in the prior art, it is irrelevant that the prior art did not recognize the key aspect of [the] invention.... An inherent structure, composition, or function is not necessarily known.")>; *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 134344, 74 USPQ2d 1398, 1406-07 (Fed. Cir. 2005) (holding that a prior art patent to an anhydrous form of a compound "inherently" anticipated the claimed hemihydrate form of the compound because practicing the process in the prior art to manufacture the anhydrous compound "inherently results in at least trace amounts of" the claimed hemihydrate even if the prior art did not discuss or recognize the hemihydrate)<.

Therefore, because prostate cancer is a cancerous angiogenesis related disease and Gleave et al. teach administering antisense oligonucleotides targeted to TRPM-2 to individuals suffering from prostate cancer and it has since been discovered that inhibition of TRPM-2 (clusterin) has the effect of reducing angiogenesis, the disclosure of Gleave et al. anticipates the instant invention.

Claims 6-8 stand rejected under 35 U.S.C. 102(e) as being anticipated by Gleave et al. (US 2003/0158130).

Claim 6 is directed to a method of reducing angiogenesis in a cancerous angiogenesis-related disease by administering to cells of the cancer a therapeutic oligonucleotide effective to reduce the amount of clusterin. Claim 7 limits the method to use of antisense oligonucleotides complementary to the sequence of human clusterin while claim 8 recites the antisense oligonucleotide is SEQ ID NO: 5.

Gleave et al. disclose and claim (see paragraphs 16, 17, 25 and table 1 as well as currently pending claims 36-39 and 42) a method of treating cancer that comprises administration of a composition that inhibits expression of TRPM-2, another name for clusterin. Gleave et al. disclose that the composition may be an antisense

oligonucleotide having the sequence designated as SEQ ID NO: 4, which is identical to the SEQ ID NO: 5 of the instant application.

At paragraph 17 and in claim 42 of Gleave et al., the method is directed to treatment of individuals having cancers that include prostate cancer, bladder cancer, ovarian cancer and lung cancer. Each of these cancers is disclosed in the instant application at page 4 as examples of cancerous angiogenesis-related diseases.

Although silent with regard to the ability of their method to reduce angiogenesis in a cancerous angiogenesis related disease, Gleave et al. disclose administration of antisense oligonucleotides targeted to TRPM-2 to cells of prostate cancer, disclosed in the instant specification at page 4 as a cancerous angiogenesis-related disease. As stated in MPEP 2112, there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of the invention, but only that the subject matter is in fact inherent in the prior art reference:

> I. SOMETHING WHICH IS OLD DOES NOT BECOME PATENTABLE UPON THE DISCOVERY OF A NEW PROPERTY
> "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). >In *In re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court held that the claimed promoter sequence obtained by sequencing a prior art plasmid that was not previously sequenced was anticipated by the prior art plasmid which necessarily possessed the same DNA sequence as the claimed oligonucleotides. The court stated that "just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel." *Id.*< See also MPEP § 2112.01 with regard to inherency and product-by-pro-cess claims and MPEP § 2141.02 with regard to inherency and rejections under 35 U.S.C. 103.
>
> II. INHERENT FEATURE NEED NOT BE RECOGNIZED AT THE TIME OF THE INVENTION
> There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure *at the time of invention*, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition by a person of ordinary skill in the art before the critical date and allowing expert testimony with respect to post-critical date clinical trials to show inherency); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004)("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention."); *Abbott Labs v. Geneva Pharms., Inc.*, 182 F.3d 1315, 1319, 51 USPQ2d 1307, 1310 (Fed.Cir.1999) ("If a product that is offered for sale inherently possesses each of the limitations of the claims, then the invention is on sale, whether or not

the parties to the transaction recognize that the product possesses the claimed characteristics."); *Atlas Powder Co. v. Ireco, Inc.*, 190 F.3d 1342, 1348-49 (Fed. Cir. 1999) ("Because 'sufficient aeration' was inherent in the prior art, it is irrelevant that the prior art did not recognize the key aspect of [the] invention.... An inherent structure, composition, or function is not necessarily known.")>; *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 134344, 74 USPQ2d 1398, 1406-07 (Fed. Cir. 2005) (holding that a prior art patent to an anhydrous form of a compound "inherently" anticipated the claimed hemihydrate form of the compound because practicing the process in the prior art to manufacture the anhydrous compound "inherently results in at least trace amounts of" the claimed hemihydrate even if the prior art did not discuss or recognize the hemihydrate)<.

Therefore, because prostate cancer is a cancerous angiogenesis related disease and Gleave et al. teach administering antisense oligonucleotides targeted to TRPM-2 to individuals suffering from prostate cancer and it has since been discovered that inhibition of TRPM-2 (clusterin) has the effect of reducing angiogenesis, the disclosure of Gleave et al. anticipates the instant invention.

(10) Response to Argument

Appellant asserts that each of the art rejections of record share the common thread that the examiner is focusing on one part of the claim and ignoring the preamble of the method. Appellant further argues that the recitation that treatment is given to "cells of the cancer" requires that the preamble be considered. The examiner agrees that the phrase "cells of the cancer" limits the preamble but disagrees that the preamble has been ignored, the limitation of the preamble has been recognized and has been considered in the rejections of record; the final rejection specifically notes that the cancers treated in each of the prior art references meet the limitations of the claims by being cancerous angiogenesis related diseases. Each of the references of record disclose not only the claimed step of administering a therapeutic oligonucleotide targeted to clusterin to cells of a cancer, but each of these cancers are cancerous angiogenesis-related diseases as defined in the instant specification at page 4.

Appellant specifically traverses the rejection over Monia et al. by arguing that the examiner has not shown that any of the cell lines tested in Monia would have any relevance or relationship to angiogenesis. The examiner is unaware of any requirement for such a showing because the rejection is not based on what cell lines were used in Monia's examples, but instead is based on the disclosure of antisense oligonucleotides targeted to clusterin, the disclosure at column 3, lines 40-46 to use these oligonucleotides to inhibit clusterin for treatment of diseases associated with expression of clusterin, the disclosure at column 2, lines 65-66 that such diseases include glioma and the teaching of Kunkel et al. that gliomas are a cancerous angiogenesis related disease as this term is defined by appellant.

Appellant further argues "nothing can be implied from the ability to treat a disease such as glioma...concerning the ability to reduce angiogenesis simply because glioma does involve angiogenesis at some stages of its progression."

As a first issue, appellant appears to be arguing the prior art fails to disclose a property that is not required by the instant claims. The instant claims make no mention that angiogenesis be present at all stages of progression, only that the therapeutic oligonucleotide be administered to cells of a cancerous angiogenesis related disease. The instant specification at page 4, third paragraph, defines the term "cancerous angiogenesis related disease" as follows:

> As used in this application, the term "cancerous angiogenesis-associated diseases" refers to cancerous diseases or conditions, wherein angiogenesis is observed as a symptom of the disease and facilitates cancer growth. Specific examples of such cancer include, without limitation, colorectal, liver, renal, lung, breast, ovarian, prostate, brain, pancreas, stomach, and cervical cancers; some leukemias and lymphomas; and AIDS-related Kaposi's sarcoma.

Neither the specification nor the claims on appeal require angiogenesis be present at all stages of progression, only that angiogenesis facilitates progression of the disease. These requirements are clearly satisfied in gliomas, as described by Kunkel et al. on page 6624, first paragraph:

> "Because glioblastomas as well as virtually all other tumors require angiogenesis to sustain growth, and malignant gliomas have been shown to be among the most densely vascularized tumors (1), antagonization of angiogenesis might be a promising treatment strategy. "

Appellant also appears to be arguing that Monia et al. does not provide an inherent disclosure of the instant claims. It is noted that once a rejection based on inherency has been made, the burden shifts to appellant to provide evidence that the prior art does not inherently possess the claimed property. Appellant has provided no such evidence to contradict the finding that Monia et al. provide an inherent disclosure of the instantly claimed method, but has merely asserted that nothing can be implied regarding angiogenesis by treating gliomas. The examiner disagrees, based on the disclosure in Monia et al. of administering antisense oligonucleotides targeted to clusterin to treat diseases associated with expression of clusterin and the subsequent discovery that clusterin expression can regulate angiogenesis, it can be implied that a prior art method that administers the same composition to the same population as that encompassed by the instant claims will have the identical result to that recited in the instant claims.

Appellant specifically traverses the rejection over Gleave et al. (US 6,900,187) by arguing that no reference to angiogenesis is made in the '187 patent. The examiner

agrees that Gleave '187 is silent with regard to angiogenesis, however Gleave '187 discloses the administration of a therapeutic oligonucleotides to cells of prostate cancer, which, as described in the instant specification at page 4, third paragraph, is a cancerous angiogenesis related disease:

> As used in this application, the term "cancerous angiogenesis-associated diseases" refers to cancerous diseases or conditions, wherein angiogenesis is observed as a symptom of the disease and facilitates cancer growth. Specific examples of such cancer include, without limitation, colorectal, liver, renal, lung, breast, ovarian, prostate, brain, pancreas, stomach, and cervical cancers; some leukemias and lymphomas; and AIDS-related Kaposi's sarcoma.

Neither the specification nor the claims on appeal require angiogenesis be present at all stages of progression, only that angiogenesis facilitates progression of the disease. Because Gleave '187 discloses the administration of a composition identical to that of the instant claims to the same population as that encompassed by the instant claims, the method of Gleave '187 will have the identical result to that of the instant claims, reduction of angiogenesis.

Appellant further argues "that the cancer mentioned in Gleave '187 may, at some stages undergo angiogenesis does not mean that angiogenesis would have occurred in the control tests reported in the Gleave patent." This argument regarding whether angiogenesis was occurring in Gleave's control tests is not persuasive because the rejection is not based on the control tests described in the Gleave patent, but on the disclosure of Gleave et al. at column 6, lines 47-56 that an antisense oligonucleotide targeted to clusterin and comprising SEQ ID NO: 5 is useful in treating prostate cancer. Appellant has shown a relationship between angiogenesis and some types of cancers, including prostate cancer. Therefore, because the method disclosed in the '187 patent, which comprises administering the claimed composition to a population suffering from a

disease specifically recited as an example of a cancerous angiogenesis related disease, the method of the '187 patent would necessarily reduce angiogenesis.

Appellant specifically traverses the rejection over Gleave 2003 by arguing there is no reference to angiogenesis in the disclosure of the application. The examiner agrees that Gleave 2003 is silent with regard to angiogenesis, however Gleave 2003 discloses the administration of a therapeutic oligonucleotides to cells of prostate cancer, which, as described in the instant specification at page 4, third paragraph, is a cancerous angiogenesis related disease:

> As used in this application, the term "cancerous angiogenesis-associated diseases" refers to cancerous diseases or conditions, wherein angiogenesis is observed as a symptom of the disease and facilitates cancer growth. Specific examples of such cancer include, without limitation, colorectal, liver, renal, lung, breast, ovarian, prostate, brain, pancreas, stomach, and cervical cancers; some leukemias and lymphomas; and AIDS-related Kaposi's sarcoma.

Neither the specification nor the claims on appeal require angiogenesis be present at all stages of progression, only that angiogenesis facilitates progression of the disease. Because Gleave 2003 discloses the administration of a composition identical to that of the instant claims to the same population as that encompassed by the instant claims, the method of Gleave 2003 will have the identical result to that of the instant claims, reduction of angiogenesis.

Appellant further argues "that the cancer mentioned in Gleave 2003 may, at some stages undergo angiogenesis does not mean that angiogenesis would have occurred in the control tests reported in the Gleave patent." This argument regarding whether angiogenesis was occurring in Gleave's control tests is not persuasive because the rejection is not based on the control tests described in the reference, but on the

disclosure of Gleave et al. at paragraphs 16 and 17 that an antisense oligonucleotide targeted to clusterin and comprising SEQ ID NO: 5 is useful in treating prostate cancer. Appellant has shown a relationship between angiogenesis and some types of cancers, including prostate cancer. Therefore, because the method disclosed in the Gleave 2003 application, which comprises administering an identical composition to a population identical to that of the instant claims that is suffering from a disease specifically recited as an example of a cancerous angiogenesis related disease, the method of the Gleave 2003 application would necessarily reduce angiogenesis.

The rulings in *In re May, (*574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978)) and *In re Tomlinson,* 363 F.2d 928, 150 USPQ 623 (CCPA 1966) as described in MPEP 2112.02 appear to be applicable to the instant claims. In *May*, the court found that for process of use claims, when a claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated. The instant application does not disclose new structures, merely the use of an old composition that claims a different result. The prior art references of record do not mention the possible different result, however as stated *In re Tomlinson*, "While the references do not show a specific recognition of that result, its discovery by appellants is tantamount only to finding a property in the old composition." (363 F.2d at 934, 150 USPQ at 628 (emphasis in original).). In the instant application, appellants have discovered a new property of antisense oligonucleotides targeted to clusterin: that they reduce angiogenesis in cancers for which angiogenesis facilitates progression of the disease. While this new property was not recognized in the prior art,

because the prior art teaches administration of the same composition to the same population as that encompassed by the instant claims, the newly discovered property was present in the prior art.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Tracy Vivlemore, Ph.D.

October 10, 2006

Conferees:

Peter Paras, Supervisory Patent Examiner

Jean Witz, Supervisory Patent Examiner

James Schultz, Primary Examiner